

ORIGINAL ARTICLE

Use of locally made off-loading techniques for diabetic plantar foot ulcer in Karachi, Pakistan

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Key words

Foot ulcer; Off loading; Pakistan

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Abstract

The aim of this study was to evaluate the effectiveness of applying locally made pressure off-loading techniques on plantar foot ulcer in individuals with diabetes. This prospective study of 70 diabetic patients was conducted at the foot clinic of Baqai Institute of Diabetology & Endocrinology. Plantar foot ulcer, stages 1A and 2A according to the University of Texas classification, was treated by using three off-loading techniques: modified foot wear (sandal), modified plaster of Paris cast with plywood platform and Scotchcast boot. The outcome was assessed at either complete wound healing (defined as complete epithelialisation) or at 12 weeks, whichever came first. Of the 70 patients, 24 were in modified foot wear group, 23 in modified plaster of Paris cast and 23 in Scotchcast boot group. There was almost equal proportion of patients healed within 12 weeks period treated with these three off-loading techniques, i.e. 22 (95.7%) for modified foot wear group, 19 (95%) for modified plaster cast and 18 (94.7%) for Scotchcast boot group. No significant difference was observed in median healing time and cumulative wound survival at 12 weeks in the three off-loading techniques. Modified foot wear group was the most cost effective (\$7) amongst the three off-loading techniques. It is concluded that in this cohort, no significant difference in healing time was observed in the three off-loading techniques, although modified foot wear (sandal) was found to be a more cost-effective treatment modality.

Introduction

Foot ulceration is the most common underlying cause of amputation in individuals with diabetes (1). Peripheral neuropathy and increased dynamic foot pressure have shown to predict an increased risk of foot ulceration (2). Several studies have demonstrated the increase in dynamic foot pressure in neuropathic foot (2–8).

High plantar foot pressure is a major risk factor in the development of plantar foot ulceration. Pressure on ulcer bed and repetitive trauma are the two major causes of persistence of ulcer once developed (9). Many methods can be used to offload an area of pressure to give the tissue time to heal without repetitive stress which leads to delayed wound healing, while keeping the patient ambulatory.

Key Messages

- although the effectiveness of off-loading neuropathic planter ulcer is well established in the developed countries, to the best of our knowledge, this is the first study that shows the effectiveness of off-loading devices in people with diabetes in Pakistan
- the aim of the study was to evaluate the effectiveness of applying locally made pressure off-loading techniques on plantar foot ulcer in individuals with diabetes
- this prospective study of 70 diabetic patients was conducted at the foot clinic of Baqai Institute of Diabetology & Endocrinology. Plantar foot ulcer, stages 1A and

2A according to the University of Texas classification is treated by using three off-loading techniques: modified foot wear (sandal), modified plaster of Paris cast with plywood platform and Scotchcast boot

- in this cohort, no significant difference in median healing time was observed in the three off-loading techniques, although modified foot wear (sandal) was found to be a more cost-effective treatment modality

Total contact cast (TCC) is considered the gold standard modality in offloading and treating diabetic neuropathic ulcer (10,11) and other modalities, such as DH Pressure Relief Walker, Charcot Restraint Orthotic Walker and Healing Sandal, are also being used for offloading the pressure at ulcer site.

Neuropathic ulcerations on the plantar aspect of the foot develop secondary to neuropathy and increase plantar peak pressure along with shear stress. Hence, decreasing the peak plantar pressure and transverse shear force is the most appropriate treatment (12), which is accomplished by offloading the ulcer site.

These offloading devices are not being used in Pakistan because of many reasons including the unavailability of materials, lack of expertise and the cost involved. To the best of our knowledge, this is the first study that shows the effectiveness of off-loading devices in people with diabetes in Pakistan.

The aim of this study was to evaluate the effectiveness of locally made pressure off-loading techniques [i.e. modified foot wear (sandal), modified plaster of Paris cast with plywood platform and Scotchcast boot] on plantar foot ulcer in individuals with diabetes.

Methodology

A prospective study of 70 diabetic patients was conducted at the foot clinic of Baqai Institute of Diabetology & Endocrinology (BIDE). Ethical approval for the study was obtained from the Institutional Review Board of the institute. Patients were randomised into one of the three off-loading techniques through computerised randomisation schedule: modified foot wear (sandal), modified plaster of Paris cast with plywood platform and Scotchcast boot, after obtaining signed informed consent.

Inclusion and exclusion criteria

Individuals with diabetes having a significant loss of protective sensation, who were unable to sense 10 g Semmes–Weinstein monofilament and a vibration perception threshold of >25 V as measured using biothesiometer, and having plantar foot ulcer stages 1A and 2A according to the University of Texas classification were included in this study. Patients who had clinical evidence of infection at ulcer site, active Charcot neuropathy, significant peripheral vascular disease defined as absent dorsalis pedis or posterior tibial pulse and inability to walk were excluded.

All the study patients were followed up in the diabetic foot clinic on weekly basis for device inspection, wound care and wound debridement if needed. A window was made for wound cleansing and debridement in both modified plaster of Paris cast with plywood platform and Scotchcast boot made of fibreglass material.

Wounds were measured and photographs were taken at each visit. The outcome was assessed at either complete wound healing (defined as complete epithelialisation) or at 12 weeks, whichever came first. The cost of the three off-loading techniques, which included the cost of materials (including plaster of Paris, cast padding, plywood, fibreglass, sandal, walking slipper) was calculated and the number of times the device had to be changed was also recorded.

Of the initially enrolled 70 patients, 62 patients completed the study, 6 were lost to follow-up and 2 left against medical advice.

Statistical analysis

Data analysis was conducted using Statistical Package for Social Sciences (SPSS), version 13.0. Analysis of variance test was used to evaluate all continuous variables between the off-loading groups and the effect of these continuous variables was also evaluated on healing of the ulcer using Mann–Whitney *U*-test. Kaplan–Meier analysis (log-rank test) was used to evaluate the healing time of each off-loading device.

Results

Of the 70 patients, 24 were in modified foot wear group, 23 in modified plaster of Paris cast and 23 in Scotchcast boot group. There was no statistically significant difference observed between the groups with respect to age, duration of diabetes and severity of neuropathy (Table 1).

Most of the ulcers were on the big toe (33.3%) in modified foot wear group, 52.2% were on heel in Scotchcast boot group, and 30.4% of the ulcers were on first metatarsal head in modified plaster of Paris cast group (Table 2).

There was almost equal proportion of patients healed within 12 weeks period treated with these three off-loading techniques. No significant difference in median healing time was seen amongst patients healed within 12 weeks. Modified foot wear group was the most cost effective (\$7) amongst these three off-loading techniques as shown in Table 3.

There was no significant difference observed in cumulative wound survival at 12 weeks in any of the three off-loading techniques (Figure 1). With regard to the complications from the treatment, two patients (one each from modified plaster of Paris cast and Scotchcast boot) had broken the device and one patient in Scotchcast boot had mild laceration of local skin area.

Discussion

Our study showed almost equal proportion of healing in modified foot wear group when compared with the other two groups. This could be because of the fact that the daily use

Table 1 Baseline characteristics

| | Modified foot wear (sandal) (n = 24) | Scotchcast boot (n = 23) | Modified plaster of Paris cast (n = 23) | Total (n = 70) | P-value |
|------------------------------------|--------------------------------------|--------------------------|---|----------------|---------|
| Age (years) | 49.79 ± 8.62 | 48.65 ± 9.03 | 52.34 ± 7.25 | 50.25 ± 8.36 | 0.312 |
| Male | 17 (70.8%) | 17 (73.9%) | 21 (91.3%) | 55 (78.6%) | 0.186 |
| Female | 7 (29.2%) | 6 (26.1%) | 2 (8.7%) | 15 (21.4%) | |
| Duration of diabetes (years) | 15.27 ± 7.04 | 13.40 ± 6.35 | 15.53 ± 7.29 | 14.71 ± 6.83 | 0.577 |
| HbA1c (%) | 10.14 ± 2.87 | 9.80 ± 1.92 | 10.53 ± 1.67 | 10.14 ± 2.22 | 0.697 |
| Vibration perception threshold (V) | 36.95 ± 11.17 | 39.13 ± 10.18 | 39.17 ± 10.36 | 38.41 ± 10.48 | 0.721 |

Data are presented as mean ± SD and n (%).

Table 2 Wound characteristics

| Site of ulcer | Modified foot wear (sandal) (n = 24) | Scotchcast boot (n = 23) | Modified plaster of Paris cast (n = 23) | Total (n = 70) | P-value |
|----------------------------------|--------------------------------------|--------------------------|---|----------------|---------|
| First metatarsal head | 6 (25%) | 3 (13%) | 7 (30.4%) | 16 (22.9%) | |
| Third metatarsal head | 2 (8.3%) | 1 (4.3%) | 3 (13%) | 6 (8.6%) | |
| Fourth metatarsal head | 0 (0%) | 0 (0%) | 2 (8.7%) | 2 (2.9%) | |
| Fifth metatarsal head | 2 (8.3%) | 3 (13%) | 2 (8.7%) | 7 (10%) | |
| Big toe | 8 (33.3%) | 4 (17.4%) | 6 (26.1%) | 18 (25.7%) | |
| Second toe | 3 (12.5%) | 0 (0%) | 0 (0%) | 3 (4.3%) | 0.002 |
| Third toe | 2 (8.3%) | 0 (0%) | 0 (0%) | 2 (2.9%) | |
| Fore foot | 0 (0%) | 0 (0%) | 1 (4.3%) | 1 (1.4%) | |
| Mid foot | 0 (0%) | 0 (0%) | 1 (4.3%) | 1 (1.4%) | |
| Heel | 1 (4.2%) | 12 (52.2%) | 1 (4.3%) | 14 (20%) | |
| Size of ulcer (cm ²) | 0.97 ± 0.54 | 1.14 ± 0.55 | 1.23 ± 0.37 | 1.12 ± 0.5 | 0.209 |

Data are presented as mean ± SD and n (%).

of walking slipper and sandal is common in our culture than shoes, therefore patients are more compliant and less reluctant to use modified sandal. It was also observed in our study that wounds healed in almost same period of time in modified foot wear group than the other two modalities.

Median time to healing of Scotchcast boot in our study was also less than the described in a retrospective study using the Scotchcast boot for offloading diabetic foot wounds (13) but nearly equal to modified plaster of Paris cast although both are non removable devices. This could be because walking directly on Scotchcast boot without using supportive sandal increases edge effect as described by Armstrong and Athanasiou (14). Moreover, modified plaster of Paris cast has a plywood support which probably decreases direct pressure on the wound.

Although there was no significant difference observed in cumulative wound survival at 12 weeks in any of the off-loading techniques but when compared in terms of cost, modified foot wear was the most cost-effective treatment modality among the three groups. These locally made devices were also much cost effective than TCC and instant total contact cast (iTCC) (15).

Different methods to offload the foot include bed rest, wheel chair, felted foam, half shoes, crutch assisted gait, therapeutic shoes, TCC and removable cast walkers (16). However, TCC is considered the gold standard off-loading modality (17).

This technique involves a moulded and minimally padded cast that maintains contact with the entire plantar aspect of the foot and the lower leg. Total contact casting has shown to be successful in healing 75–100% of diabetic neuropathic

ulcerations (18). Although most of the physicians understand the effectiveness of this gold standard off-loading technique in relieving plantar foot pressure, less than 2% of the centres are using this treatment modality (19). Healing time for TCC ranges from four to eight weeks (20–27).

Both Armstrong and Katz also showed the effectiveness of TCC and removable cast walker (RCW) rendered irremovable (iTCC) (15). Because improper cast application can cause skin irritation and even in some cases ulceration, it requires a physician or cast technician with training or experience to safely apply a TCC.

Unfortunately, the technicians in our institute, who can perform the application of TCC are not available. Furthermore, the extra cost of RCW and sometimes the casting material are the other limitations for using these modalities in our low-resourced society. Hence, we are compelled to use the locally made off-loading devices which are more cost effective and increase patient compliance. Similarly, there are some studies from India that show the effectiveness of locally made, low-cost off-loading techniques (28,29).

Our study has some limitations such as: the sample size was small to detect possible differences which could have been present. Moreover, patients with ischaemic and infected foot ulcers were not included in the study.

Conclusion

In this patient cohort, no significant difference in healing time was observed in the three off-loading techniques although modified foot wear (sandal) was found to be a

Table 3 Outcome of the patients

| | Modified foot wear (sandal) (n = 23) | Scotchcast boot (n = 17) | Modified plaster of Paris cast (n = 20) | Total (n = 62) | P-value |
|----------------------|---|-----------------------------|--|-------------------|---------|
| Healing time (days)* | 34.0 | 46.0 | 45.0 | 42.50 | 0.767 |
| Healed (%) | 22 (95.7%) | 18 (94.7%) | 19 (95%) | 59 (95.2%) | 0.99 |
| Cost (\$) | 7 | 35 | 20 | — | 0.000 |

Data are presented as mean \pm SD and n (%).

*Median healing time.

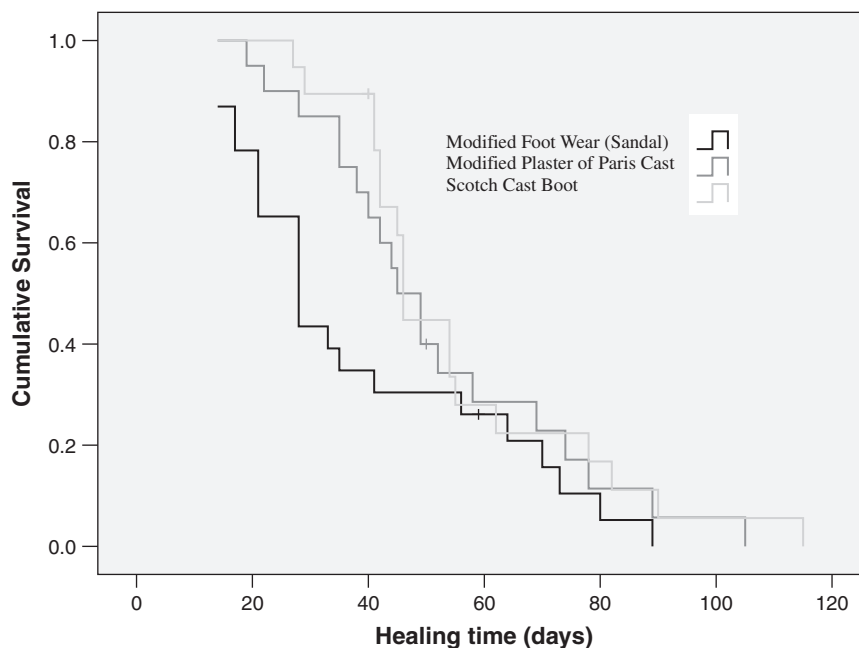


Figure 1 Cumulative wound survival at 12 weeks.

more cost-effective treatment modality. Furthermore, large-scale studies are needed to show the effectiveness of off-loading treatment modalities other than TCC and iTCC in low-resourced countries.

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Author contributions

ZM, AB, JA and SIZ performed the conception and design or acquisition of data or analysis and interpretation of data. ZM, AB, JA, MYA, AF and SIH drafted the article and revised it critically for important intellectual content. ZM, AB, JA, MYA, SIZ and AF approved the final version of the article to be published.

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